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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,920	02/01/2000	ARNE EEK	1103326-0603	6956

7470 7590 02/08/2005

WHITE & CASE LLP  
PATENT DEPARTMENT  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/463,920

**Applicant(s)**

EEK ET AL.

**Examiner**

Susan T. Tran

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-32 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) 28-30, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-27, 31, 32 and 38-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment filed 12/08/04.

In view of the amendment filed on 12/08/04, PROSECUTION IS HEREBY REOPENED. The new rejections are set forth below.

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42).

Tari teaches omeprazole-enprostil combination useful for the treatment of peptic ulcer (see abstract, page 1741). Tari teaches omeprazole-enprostil can be administered per os (by mouth) (page 1742, 4<sup>th</sup> paragraph).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42), and Depui et al.

Tari is relied upon for the reason stated above. Tari is silent as to the specific oral dosage form.

Depui teaches an oral composition comprising combination of NSAID and proton pump inhibitor, such as omeprazole, lansoprazole, pantoprazole, single enantiomer, or salts thereof including magnesium salt; carriers; and excipients (columns 5-8). The composition is useful for the treatment of gastrointestinal disorders (column 1, lines 10-18). The composition can be in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14, and Fig. 6). Thus, it would have been obvious for one of ordinary skill in the art to modify the oral dosage form of Tari in view of the oral dosage form of Depui, because the references teach that it is well known to formulate omeprazole in controlled/sustained release oral dosage is useful for the treatment of gastrointestinal disorders.

Claims 31, 32, 35 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42), in view of Depui et al., and Shell US 5,582,837.

Tari and Depui are relied upon for the reasons stated above. The references are silent as to the teachings of the use of calcium channel blocker.

Shell teaches sustained release dosage form containing calcium channel blockers useful for the treatment of gastric diseases (columns 3-4). Hence, it would have been prima facie obvious for one of ordinary skill in the art to prepare composition of Tari and Depui with calcium channel blocker in view of the teaching of Shell, because

the references teach the advantageous results of oral formulation useful for treating gastrointestinal disorders. The expected result would be a single dosage form comprising combination of proton pump inhibitor, calcium channel blocker, and prostaglandin for the treatment of gastrointestinal disorders.

### ***Response to Arguments***

Applicant's arguments filed 12/08/04 has been fully considered but they are not persuasive.

Applicant argues that Tari does not disclose an oral dosage form of the combination of omeprazole-enprostil. Contrary to the applicant's argument, Tari does disclose combination of omeprazole-enprostil for oral administration (see 4<sup>th</sup> paragraph at page 1742). Tari is only deficient in the sense that Tari does not explicitly teach the specific structural of an oral dosage form.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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